REMARKS

Claims 18-31 are pending. Claim 22 has been amended to correct a typographical error.

Claims 22-31 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,464,631 to Hoover (hereinafter, "the Hoover patent") in view of U.S. Patent No. 5,785,994 to Wong, *et al.* (hereinafter, "the Wong patent"). The rejection is improper because one of ordinary skill in the art would not have been motivated to combine the teachings of the cited patents. Patent claims cannot be found obvious in view of a combination of references unless the prior art itself suggests the desirability of the combination. *Berghauser v. Dann*, 204 U.S.P.Q. 393 (D.D.C. 1979); *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 U.S.P.Q. 929 (Fed. Cir. 1984). "A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." *In re Kotzab*, 217 F.3d 1365, 1369, 55 U.S.P.Q.2d 1313, 1316 (Fed. Cir. 2000). To establish a prima facie case of obviousness, "there must be some teaching, suggestion or motivation in the prior art to make the specific combination that was made by the applicant." *In re Dance*, 160 F.3d 1339, 1343, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998). "In other words, the examiner must show reasons that the skilled artisan, confronted with the same problem as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998).

There is no evidence of record indicating that those of ordinary skill would have been motivated to combine the teachings of the Hoover patent and the Wong patent. The Hoover patent discloses a capsule wherein the medicament in a caplet body is partially encapsulated with one-half of an empty gelatin capsule. (*See, e.g.*, column 3, lines 49-54; column 5, lines 57-59). The Wong patent, however, discloses a tablet dosage form, not a capsule, and the Examiner has not identified any motivation for one skilled in the art to combine the capsule teachings of the Hoover patent with the tablets disclosure of the Wong patent.

Indeed, there is no reason to believe that those of ordinary skill would have even considered the Hoover patent to be relevant to Applicants' claimed inventions. The Hoover patent discloses a capsule that is one color and a caplet that is another (*see, e.g.* column 6, lines 20-25), whereas the present claims, for example, are directed to multiple-layered tablets in which each layer has a different colorant (*see, e.g.*, claims 18-31). The Examiner has not identified any motivation that those of ordinary skill seeking to develop the claimed subject matter would have had to consult the Hoover patent. Although the Examiner alleges that it would have been obvious to prepare "a sustain[ed] release dosage form as suggested by Hoover . . . using Wong's methods" (Office Action at page 4), much more is required to support rejection under Section 103.

Claims 18-31 are newly rejected under 35 U.S.C. § 103(a) as being unpatentable over the Hoover patent and U.S. Patent No. 5,824,338 to Jacobs (hereinafter, "the Jacobs patent") in view of the Wong patent and further in view of U.S. Patent No. 5,094,786 to Nagashima, U.S. Patent No. 5,558,231 to Weier, or U.S. Patent No. 5,422,831 to Misra. Applicants traverse this rejection because the Examiner has provided no showing why one of ordinary skill in the art would have combined the teachings of the above-cited references to obtain the

present invention. The Jacobs patent, for example, does not provide the motivation that, as noted above, would have been missing with respect to combination of the Hoover and Wong patents. Like the Hoover patent, the Jacobs patent teaches a caplet that is covered by a capsule having a land 14 that is not found in the dosage forms of the present invention. (column 3, lines 13-30). The caplet shells are also made to overlap as seen in Figure 5 or may be butt-joined. (column 3, lines 36-39). This dosage form is quite different from the layered tablets to which the instant claims are directed. Also, there is no teaching in the Jacobs patent relating to using a colorant in layered dosage forms. The examiner has not identified any disclosure within the cited references that would have motivated one of ordinary skill in the art to combine their respective teachings or apply such the teachings to development of any claimed invention. Without such a showing, Applicants respectfully request withdrawal of the rejection for alleged obviousness.

In view of the foregoing, Applicants submit that the claims presently before the Examiner are in condition for ready allowance. An early Office Action to that effect is, therefore, earnestly solicited.

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